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(54) **ANALYSIS SYSTEM, ANALYSIS DEVICE, AND MANAGEMENT DEVICE**

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(51) **Int. Cl.**

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G06F 19/00	(2011.01)
G01N 35/00	(2006.01)
G01N 31/22	(2006.01)

(52) **U.S. Cl.**

CPC ***G06F 19/70*** (2013.01); ***G01N 31/22*** (2013.01); ***G01N 33/50*** (2013.01); ***G01N 35/00871*** (2013.01); *G01N 2035/00673* (2013.01); *G01N 2035/00851* (2013.01)

(58) **Field of Classification Search**

CPC G01N 33/50
USPC 702/22
See application file for complete search history.

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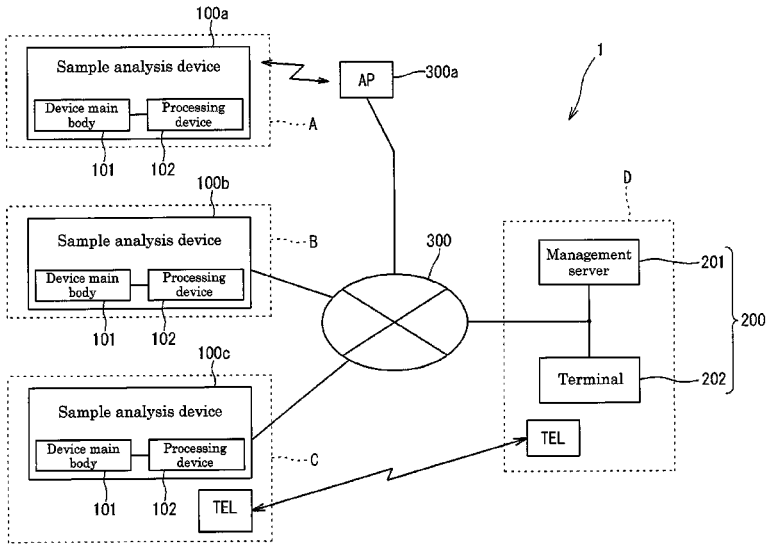
(57) **ABSTRACT**

An analysis system comprising: an analysis device that analyzes a sample using a reagent and that performs the analysis of the sample in accordance with a measurement parameter measured in relation to a reagent to be used; and a management device communicably connected to the analysis device via a network; wherein the analysis device includes a first control unit that enables execution of processing for accepting a registration of the measurement parameter, and when the measurement parameter is registered, executes processing for transmitting to the management device transmission information including information indicating that the measurement parameter is registered; and the management device includes a second control unit that executes a receiving process of receiving the transmission information transmitted from the analysis device and an output process of outputting information indicating that the measurement parameter is registered in the analysis device based on the received transmission information is disclosed.

19 Claims, 12 Drawing Sheets



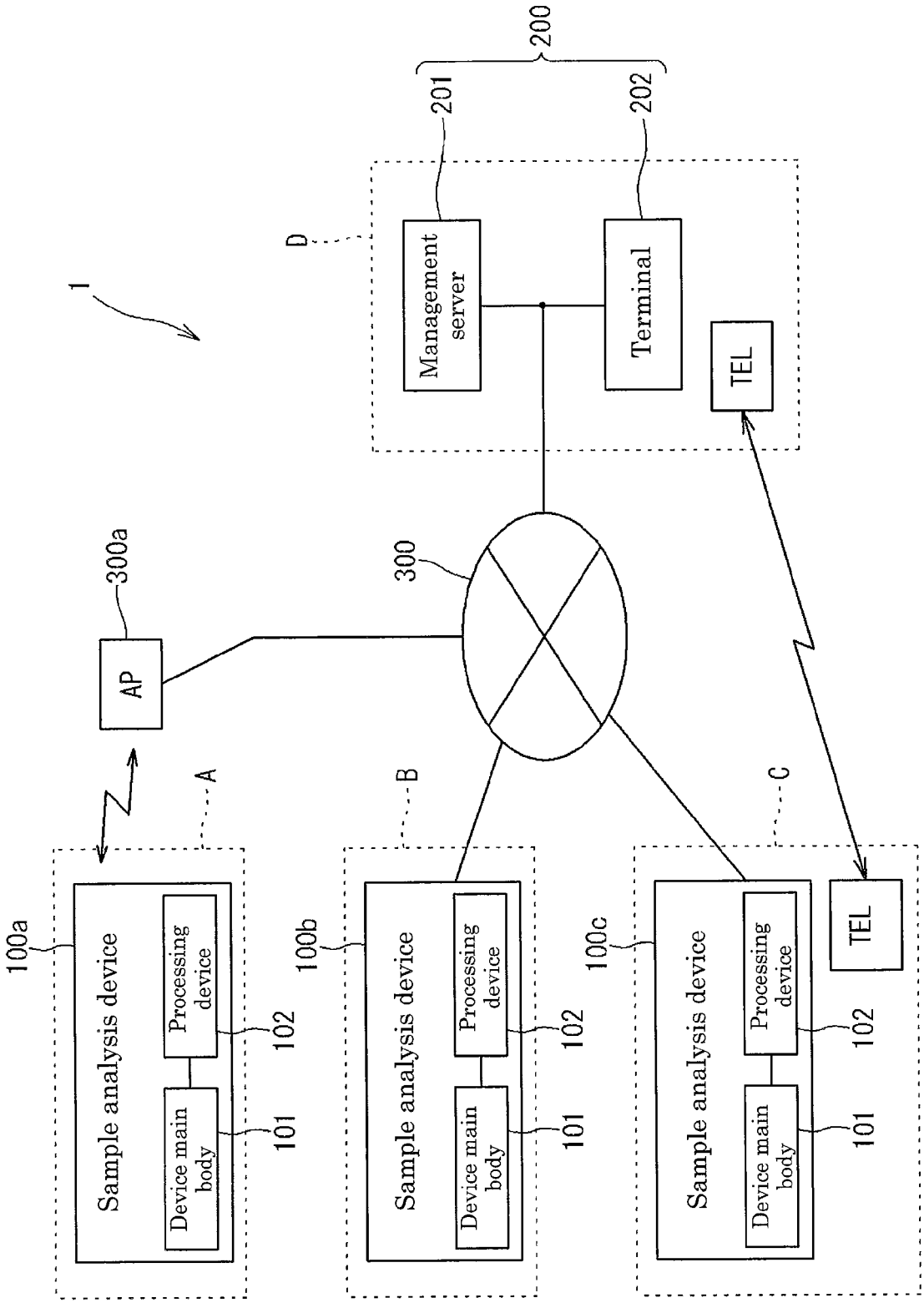

1
200
201
202
D
Management server
Terminal
TEL
300
300a
AP
A
B
C
100a
100b
100c
Sample analysis device
Processing device
Device main body
101
102
TEL

FIG. 1

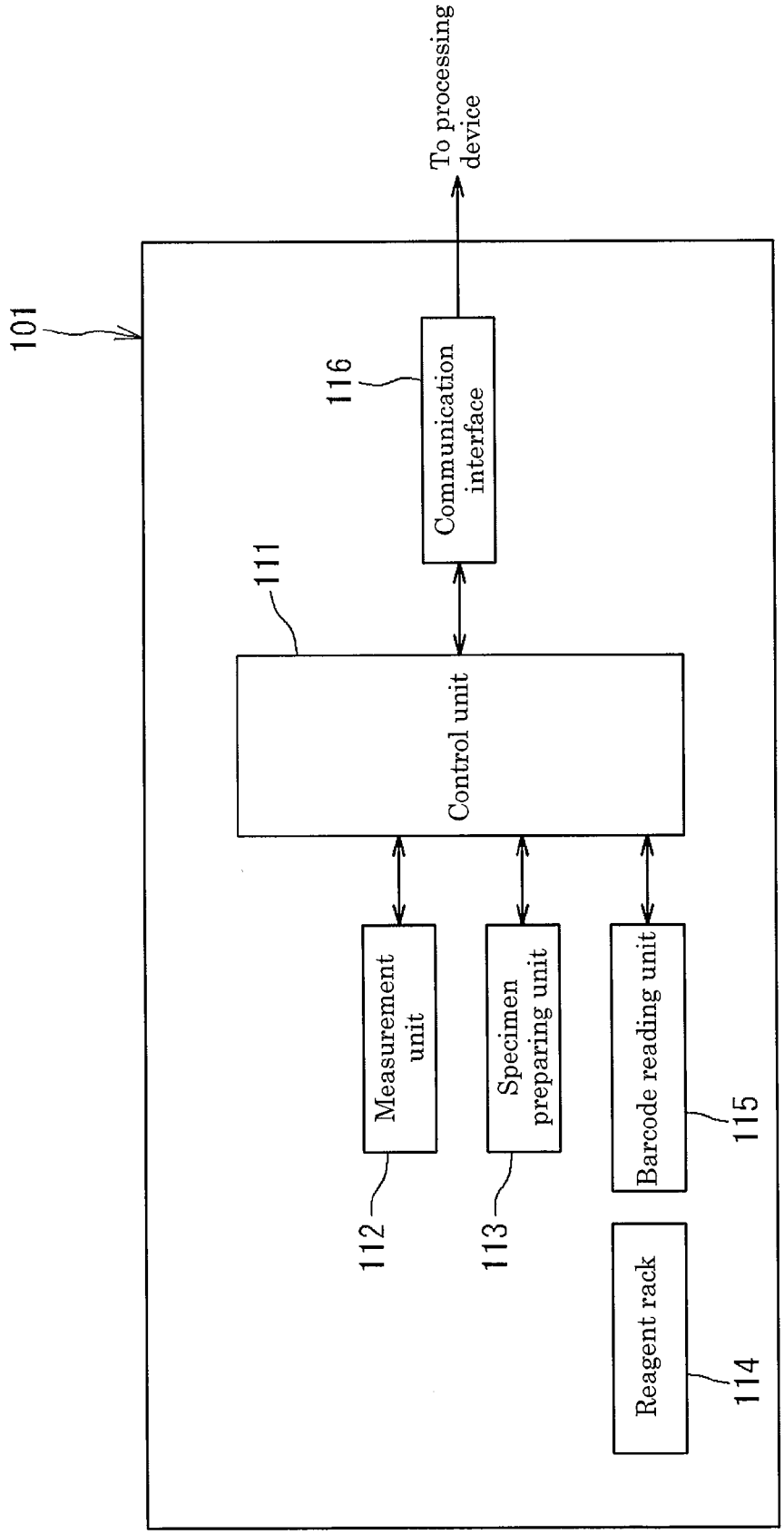

To processing device
101
116
Communication interface
111
Control unit
Measurement unit
Specimen preparing unit
Barcode reading unit
112
113
115
Reagent rack
114

FIG. 2

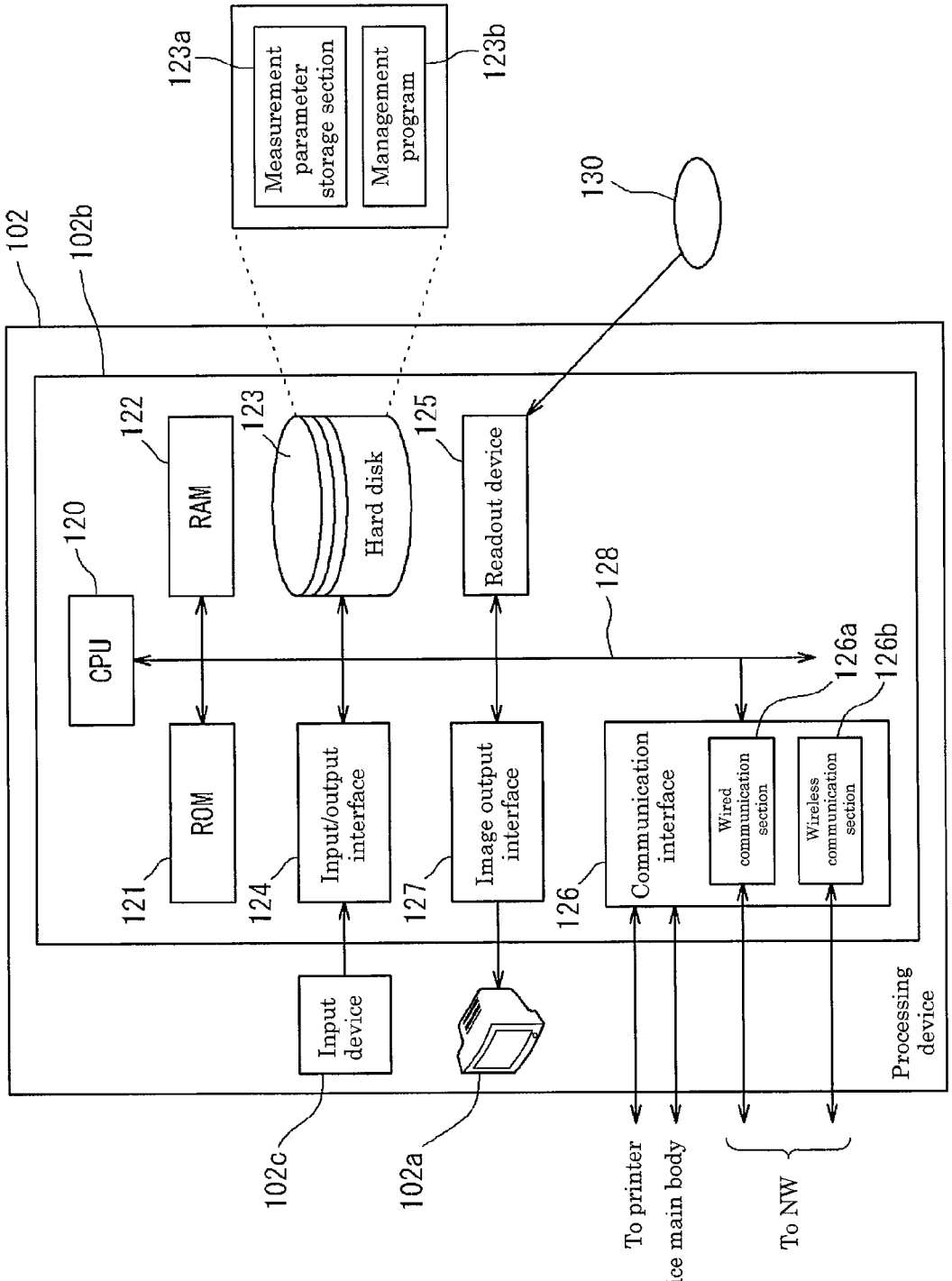

123a
Measurement parameter storage section
Management program
123b
130
102
102b
122
RAM
123
Hard disk
125
Readout device
120
CPU
128
126a
126b
ROM
Input/output interface
Image output interface
Communication interface
Wired communication section
Wireless communication section
121
124
127
126
Input device
Processing device
102c
102a
To printer
To analysis device main body
To NW

FIG. 3

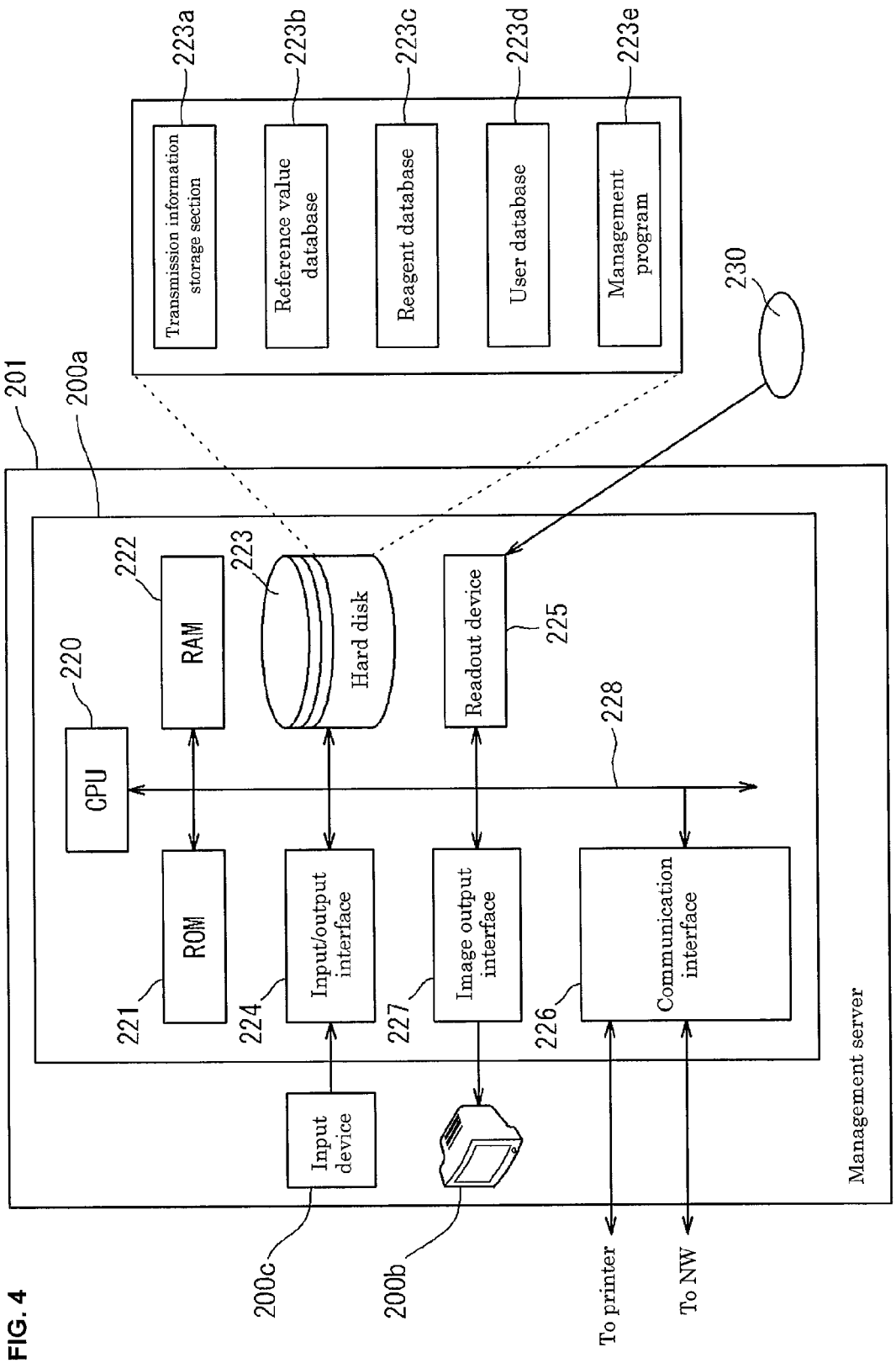

223a
223b
223c
223d
223e
Transmission information storage section
Reference value database
Reagent database
User database
Management program
230
201
200a
222
223
RAM
Hard disk
Readout device
225
220
228
CPU
ROM
Input/output interface
Image output interface
Communication interface
221
224
227
226
Input device
Management server
200c
200b
To printer
To NW

FIG. 4

FIG. 5

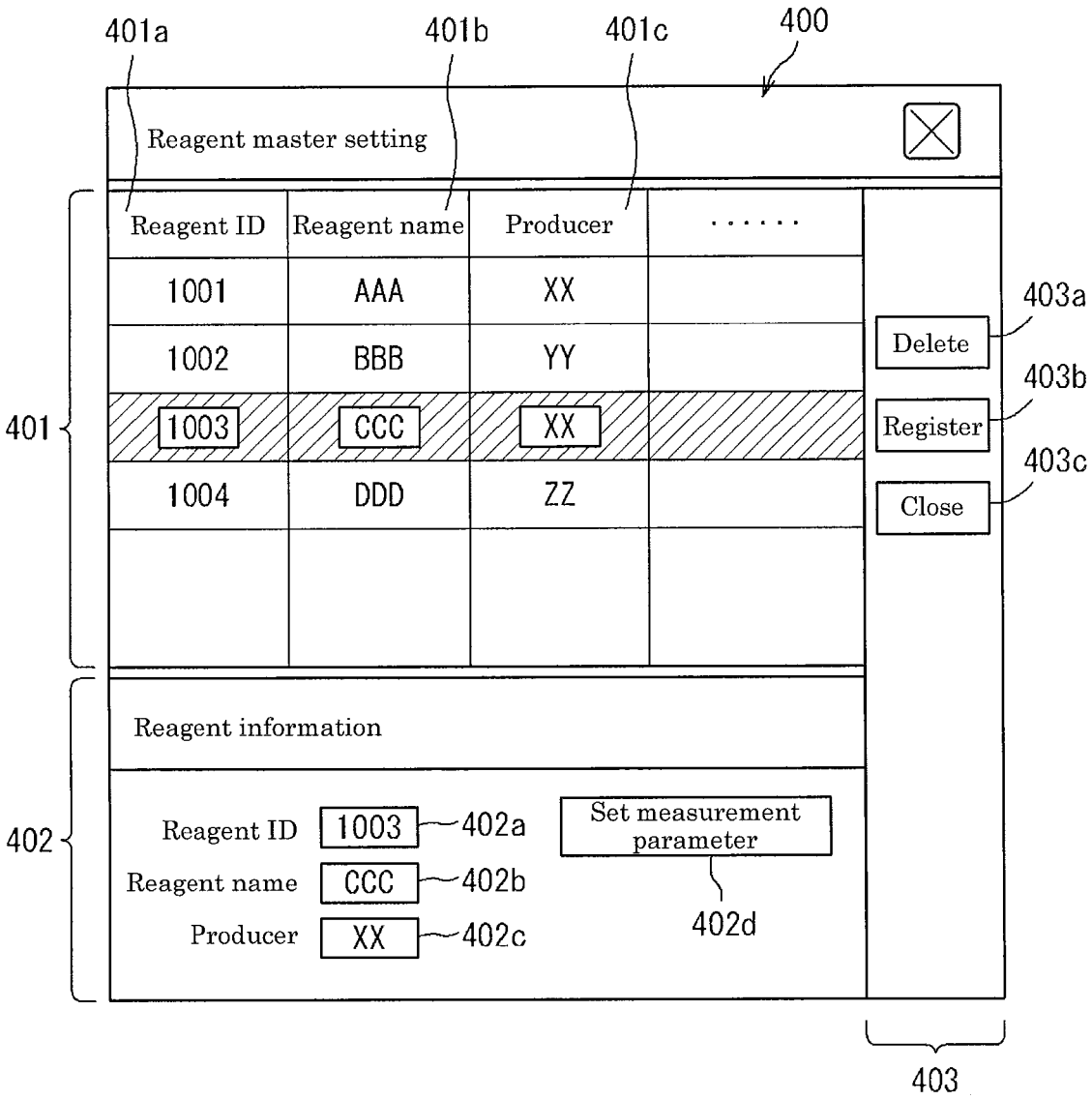
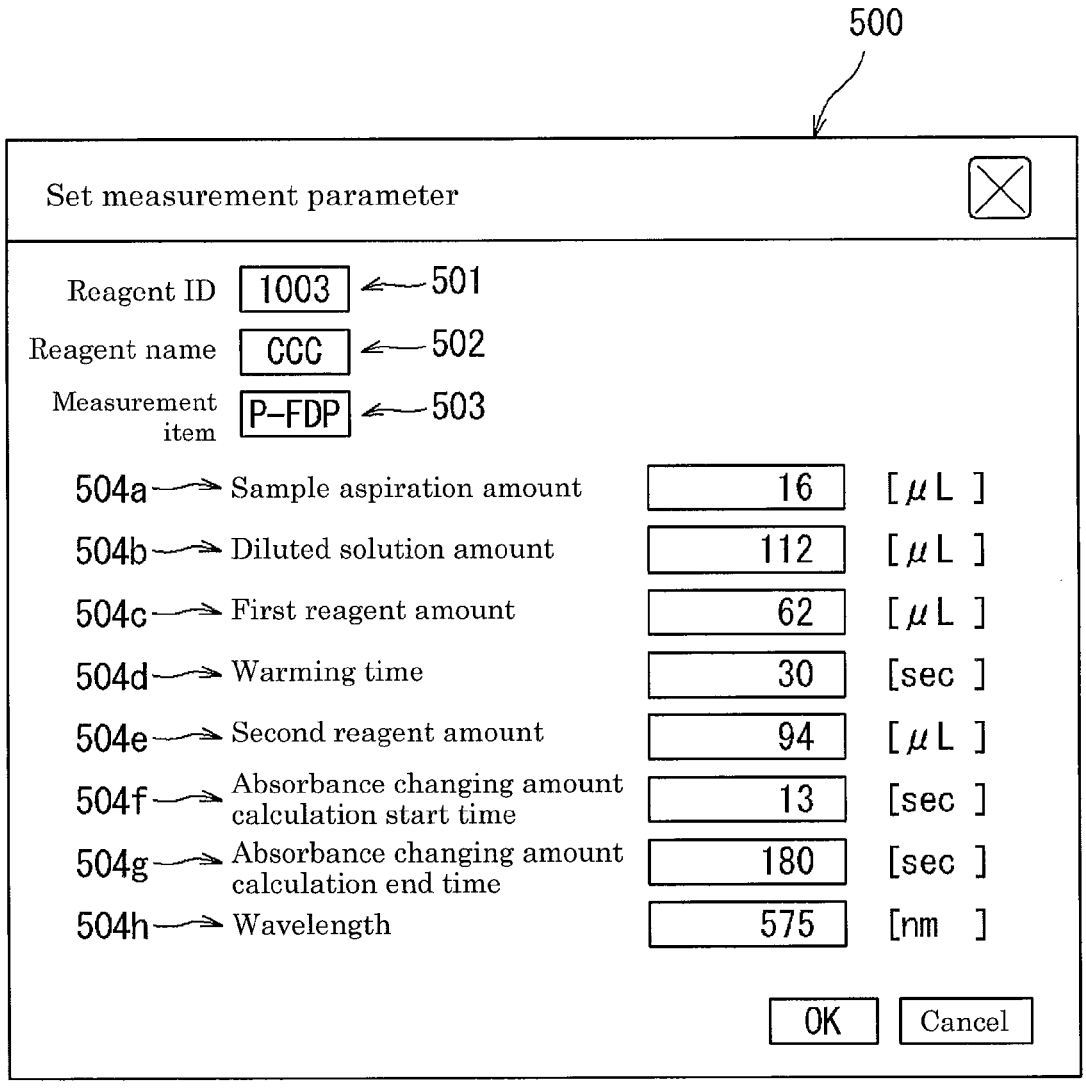

401a
401b
401c
400
Reagent master setting
Reagent ID
Reagent name
Producer
. . . . . .
1001
AAA
XX
1002
BBB
YY
1003
CCC
XX
1004
DDD
ZZ
401
403a
Delete
403b
Register
403c
Close
Reagent information
Reagent ID
1003
402a
Reagent name
CCC
402b
Producer
XX
402c
Set measurement parameter
402d
402
403

FIG. 6


500
Set measurement parameter
Reagent ID
1003
501
Reagent name
CCC
502
Measurement item
P-FDP
503
504a
Sample aspiration amount
16
[μL]
504b
Diluted solution amount
112
[μL]
504c
First reagent amount
62
[μL]
504d
Warming time
30
[sec]
504e
Second reagent amount
94
[μL]
504f
Absorbance changing amount calculation start time
13
[sec]
504g
Absorbance changing amount calculation end time
180
[sec]
504h
Wavelength
575
[nm]
OK
Cancel

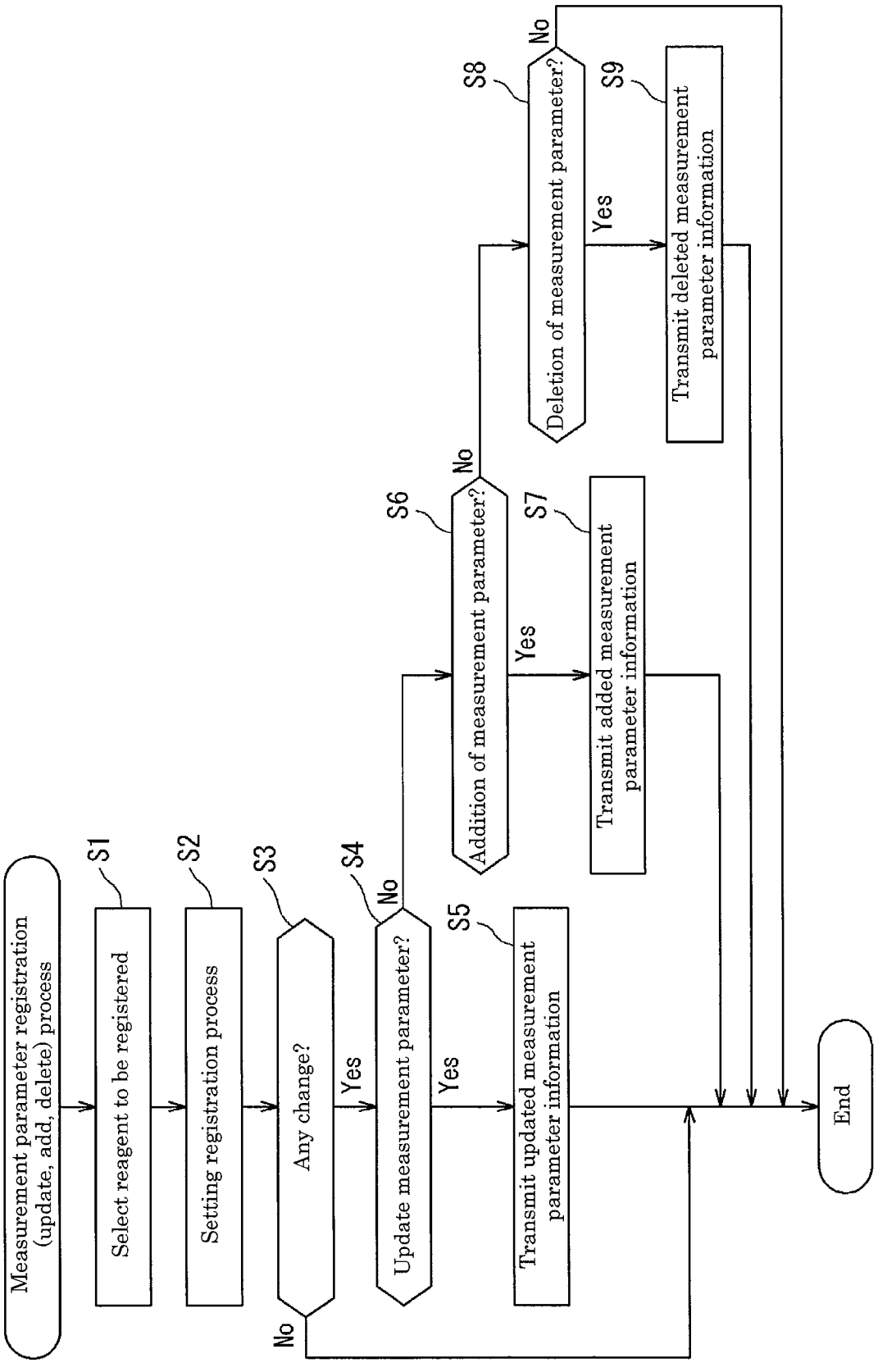

Measurement parameter registration (update, add, delete) process
S1
Select reagent to be registered
S2
Setting registration process
S3
Any change?
Yes
No
S4
Update measurement parameter?
Yes
No
S5
Transmit updated measurement parameter information
S6
Addition of measurement parameter?
Yes
No
S7
Transmit added measurement parameter information
S8
Deletion of measurement parameter?
Yes
No
S9
Transmit deleted measurement parameter information
End

FIG. 7

FIG. 8

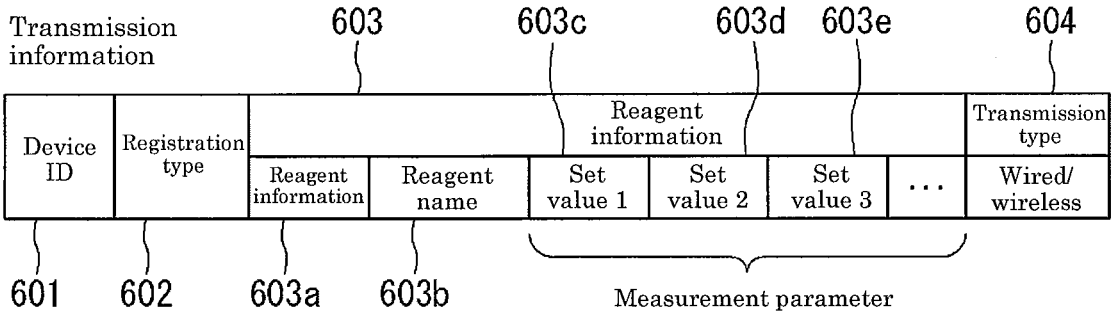
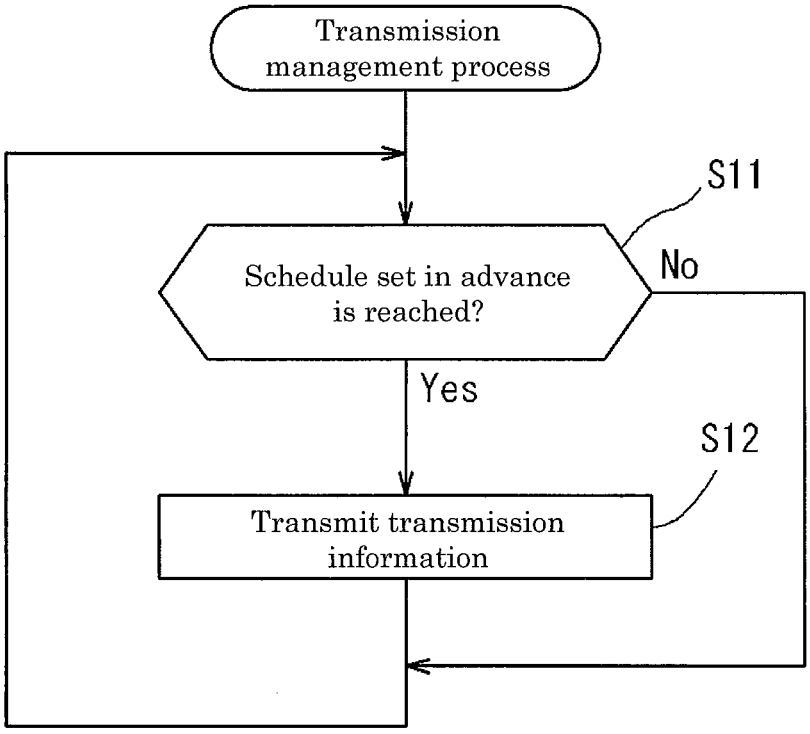

Transmission information
603
603c
603d
603e
604
Device ID
Registration type
Reagent information
Reagent information
Reagent name
Set value 1
Set value 2
Set value 3
...
Transmission type
Wired/ wireless
601
602
603a
603b
Measurement parameter

FIG. 9


Transmission management process
S11
Schedule set in advance is reached?
No
Yes
S12
Transmit transmission information

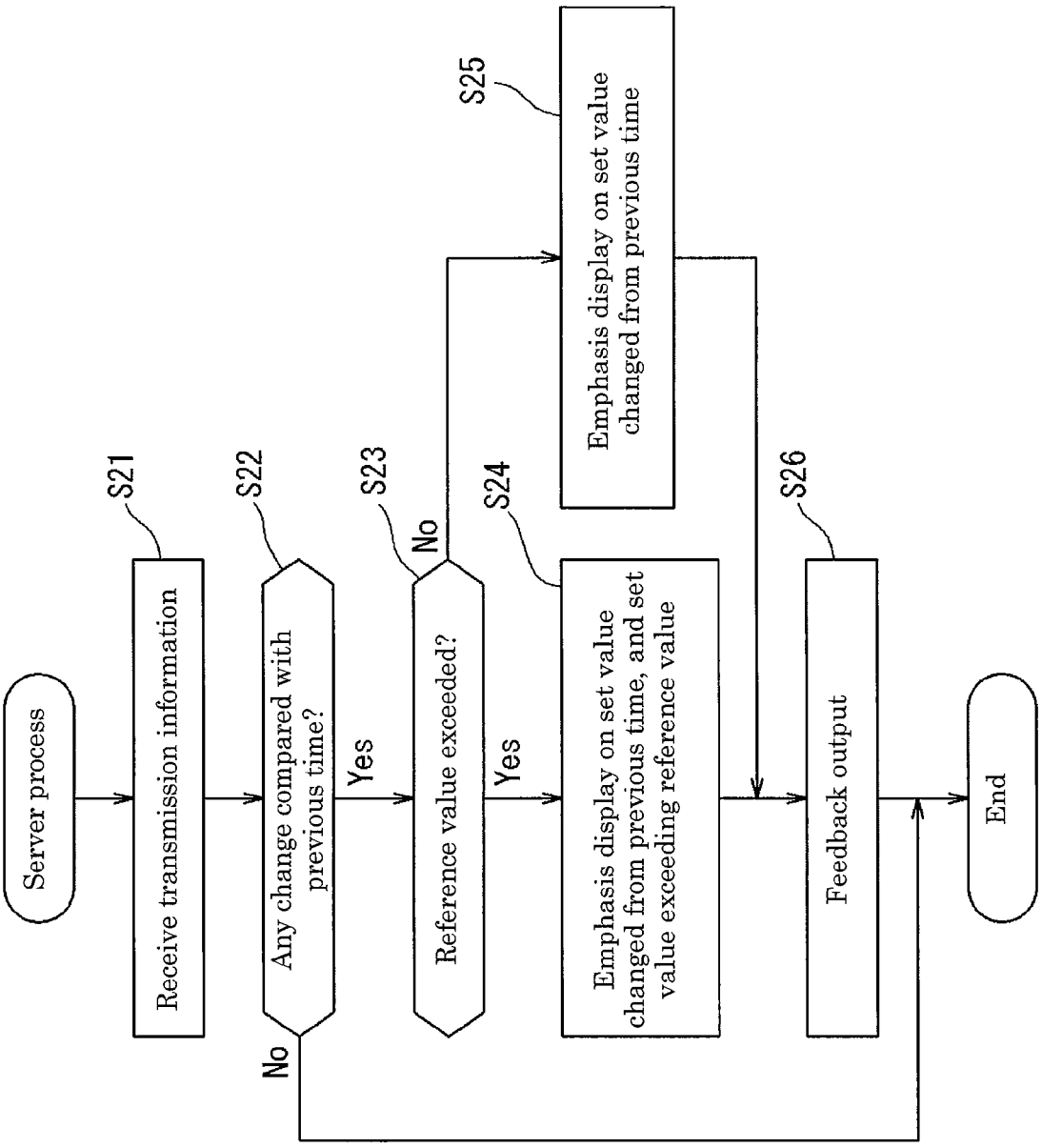

Server process
S21
Receive transmission information
S22
Any change compared with previous time?
Yes
No
S23
Reference value exceeded?
Yes
No
S24
Emphasis display on set value changed from previous time, and set value exceeding reference value
S25
Emphasis display on set value changed from previous time
S26
Feedback output
End

FIG. 10

FIG. 11

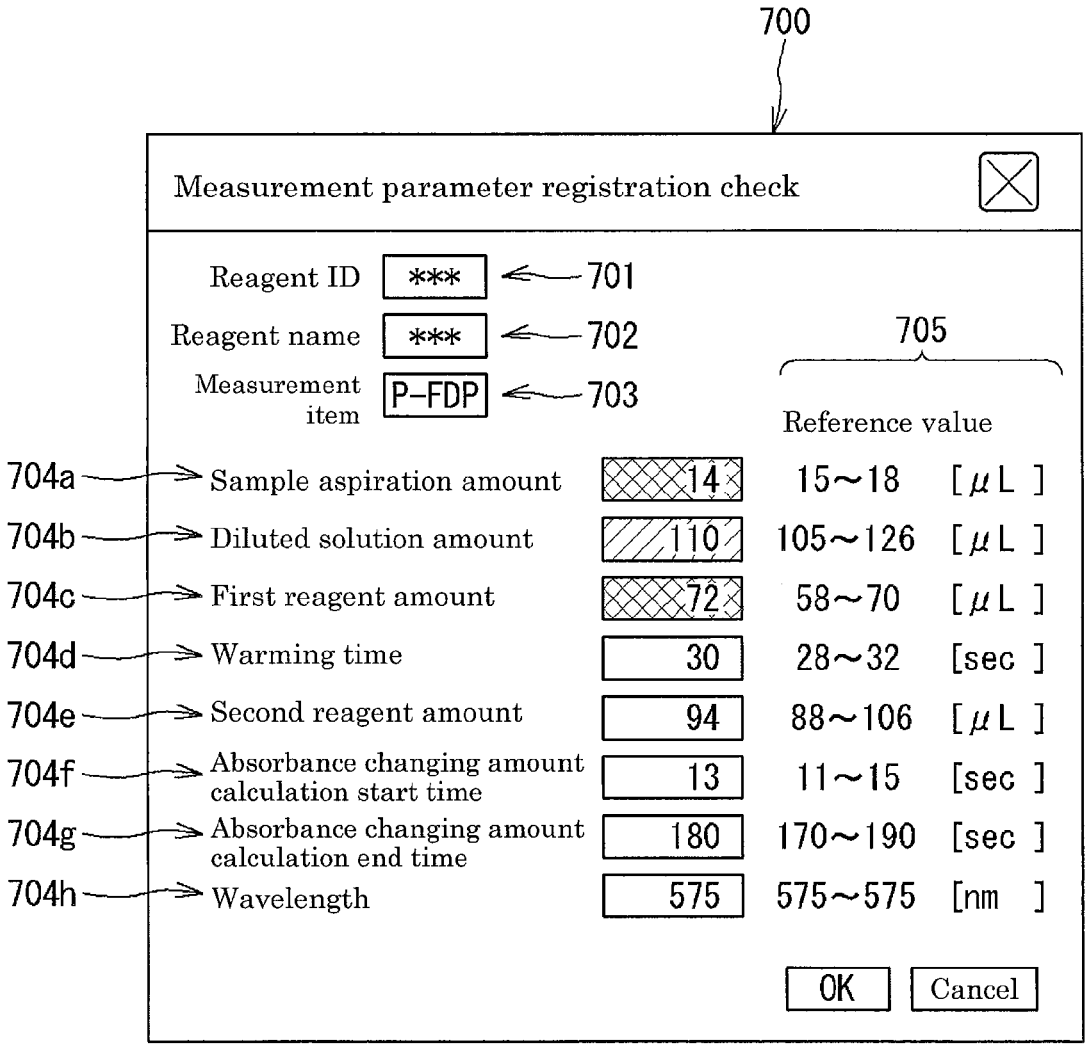
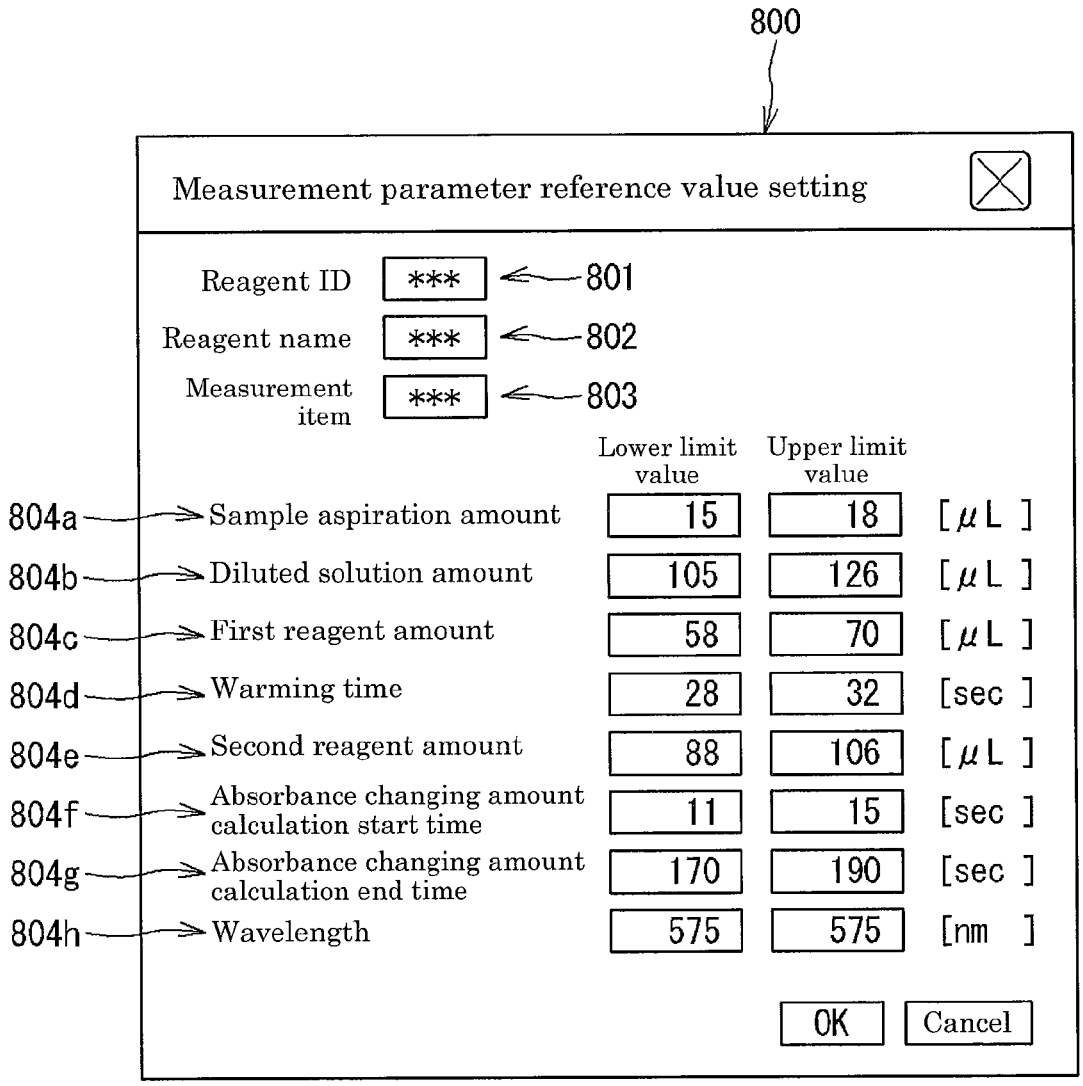

700
Measurement parameter registration check
Reagent ID
***
701
Reagent name
***
702
Measurement item
P-FDP
703
705
Reference value
704a
Sample aspiration amount
14
15~18 [μL]
704b
Diluted solution amount
110
105~126 [μL]
704c
First reagent amount
72
58~70 [μL]
704d
Warming time
30
28~32 [sec]
704e
Second reagent amount
94
88~106 [μL]
704f
Absorbance changing amount calculation start time
13
11~15 [sec]
704g
Absorbance changing amount calculation end time
180
170~190 [sec]
704h
Wavelength
575
575~575 [nm]
OK
Cancel

FIG. 12


800
Measurement parameter reference value setting
Reagent ID
***
801
Reagent name
***
802
Measurement item
***
803
Lower limit value
Upper limit value
804a
Sample aspiration amount
15
18
[μL]
804b
Diluted solution amount
105
126
[μL]
804c
First reagent amount
58
70
[μL]
804d
Warming time
28
32
[sec]
804e
Second reagent amount
88
106
[μL]
804f
Absorbance changing amount calculation start time
11
15
[sec]
804g
Absorbance changing amount calculation end time
170
190
[sec]
804h
Wavelength
575
575
[nm]
OK
Cancel

ANALYSIS SYSTEM, ANALYSIS DEVICE, AND MANAGEMENT DEVICE

RELATED APPLICATIONS

This application is a continuation of PCT/JP2013/001970 filed on Mar. 22, 2013, which claims priority to the Japanese Application No. 2012-077486 filed on Mar. 29, 2012. The entire contents of these applications are incorporated herein by reference.

TECHNICAL FIELD

The present invention relates to an analysis system, an analysis device, and a management device.

BACKGROUND ART

In analysis devices of biochemical, coagulation, and the like, a reagent for the same measurement item is sold from plural reagent manufacturers. The user selects one of a plurality of reagents, and uses the same for analysis. Each of the reagents has different properties, and thus a measurement parameter such as a dispensing amount, a reaction time, and the like of the reagent needs to be set and registered for each reagent. The analysis device stores the measurement parameter and analyzes a sample in accordance with the stored measurement parameter.

It is desirable that the measurement parameter can be registered (new registration and change) from the standpoint of ensuring the convenience of the user. However, since the measurement parameter is not frequently changed, an appropriate measurement parameter may not be registered due to operation mistakes, lack of knowledge, and the like.

If an appropriate measurement parameter is not registered, the measurement result by the analysis device might be adversely affected.

U.S. Patent Application Publication No. US2010/0054997 discloses an automatic analysis device that includes an operation unit to which an analysis parameter can be input, and in which the analysis parameter can be changed.

In the automatic analysis device described in U.S. Patent Application Publication No. US2010/0054997, in order to prevent the user from accidentally changing the parameter, a password is required when changing the parameter.

In the analysis device described in U.S. Patent Application Publication No. US2010/0054997, the parameter can be suppressed from being accidentally changed by requesting a password, but regardless of such measures, a case in which an erroneous parameter is registered cannot be handled.

SUMMARY OF THE INVENTION

The scope of the present invention is defined solely by the appended claims, and is not affected to any degree by the statements within this summary.

An analysis system according to the first aspect of the present invention relates to an analysis system including an analysis device that analyzes a sample using a reagent and that performs the analysis of the sample in accordance with a measurement parameter measured in relation to a reagent to be used; and a management device communicably connected to the analysis device via a network; wherein the analysis device includes a first control unit that enables execution of processing for accepting a registration of the measurement parameter, and when the measurement parameter is registered, executes processing for transmitting to the management device transmission information including information indicating that the measurement parameter is registered; and the management device includes a second control unit that executes a receiving process of receiving the transmission information transmitted from the analysis device and an output process of outputting information indicating that the measurement parameter is registered in the analysis device based on the received transmission information.

An analysis device according to the second aspect of the present invention relates to an analysis device that analyses a sample using a reagent and that performs the analysis of the sample in accordance with measurement parameter set in relation to a reagent to be used, the analysis device being communicably connected to a management device via a network; the analysis device including a control unit that enables execution of processing for accepting registration of the measurement parameter, and when the measurement parameter is registered, executes processing for transmitting to the management device transmission information including information indicating that the measurement parameter is registered.

A management device according to the fourth aspect of the present invention relates to a management device communicably connected via a network to an analysis device that analyses a sample using a reagent and that performs the analysis of the sample in accordance with measurement parameter set in relation to a reagent to be used, the management device including a control unit that executes a receiving process of receiving transmission information including information indicating that the measurement parameter is registered in the analysis device from the analysis device, and an output process of outputting the information indicating that the measurement parameter is registered in the analysis device based on the received transmission information.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows one example of an overall configuration diagram of an analysis system.

FIG. **2** shows one example of a configuration diagram of a device main body of an analysis device.

FIG. **3** shows one example of a configuration diagram of a processing device of the analysis device.

FIG. **4** shows one example of a configuration diagram of a management server.

FIG. **5** is a schematic view showing one example of a reagent master setting screen.

FIG. **6** is a schematic view showing one example of a measurement parameter setting screen.

FIG. **7** shows one example of a flowchart of a measurement parameter registration process.

FIG. **8** is a schematic view showing one example of a data structure of transmission information.

FIG. **9** shows one example of a flowchart of a transmission management process.

FIG. **10** shows one example of a flowchart of a server process.

FIG. **11** is a schematic view showing one example of a measurement parameter registration check screen.

FIG. **12** is a schematic view showing one example of a measurement parameter reference value setting screen.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

An embodiment of a sample analysis device according to the present invention will be hereinafter described in detail with reference to the accompanying drawings.

[1. Overall Configuration of Analysis System]

FIG. **1** shows an analysis system **1** according to an embodiment. The analysis system **1** includes analysis devices **100***a*, **100***b*, **100***c*, and a management device **200**.

The analysis devices **100***a*, **100***b*, **100***c* (hereinafter simply referred to as "analysis device **100**" if the plurality of analysis devices does not need to be distinguished) are respectively installed in inspection facilities A, B, C and are connectable to a network **300** such as the Internet.

The management device **200** includes a management server **201** and a terminal device **202**, and is installed in a customer support center D. The management server **201** and **202** are connected by the LAN, and are respectively connectable to the network **300** such as the Internet, and the like.

The customer support center D is a facility for a vendor who performs the maintenance of the analysis device **100**, and is provided to collect various types of information from the analysis device **100** and perform management with respect to the analysis device **100**.

The analysis device **100** is a device for optically measuring and analyzing the amount of specific substance, the degree of activity, and the like associated with coagulation and fibrinolytic function of blood, for example. In the analysis device **100**, for example, blood plasma is used, for the sample.

The analysis device **100** performs optical measurement of a sample using coagulation time method, synthetic substrate method, and immune nephelometry. The coagulation time method used in the present embodiment is a measurement method for detecting the process in which the sample coagulates as change in transmissive light. The measurement items of the coagulation time method include PT (prothrombin time), APTT (activity portion thromboplastin time), Fbg (fibrinogen amount), and the like. The measurement items of the synthesis substrate method include ATIII, and the like. The measurement items of the immune nephelometry include D dimer, FDP, and the like.

As shown in FIGS. **1** to **3**, the analysis device **100** includes a device main body **101** and a processing device **102**. The device main body **101** and the processing device **102** are communicably connected.

The device main body **101** mainly performs the measurement of the sample. The processing device **102** performs processes such as the analysis process of the measurement result obtained by the device main body **101**, the communication with the management device **200** (management server **201**), and the like.

As shown in FIG. **2**, the device main body **101** includes a control unit **111**, a measurement unit **112**, a specimen adjusting unit **113**, a reagent rack **114**, a barcode reading unit **115**, a communication interface **116**, and the like.

The control unit **111** controls each unit in the device main body **101**, and performs the control for reagent preparation, measurement, and the like. The control unit **111** also performs the process of communication carried out with the processing device **102** through the communication interface **116**.

The measurement unit **112** performs the measurement (optical measurement) of the specimen prepared from the sample, and outputs the measurement result. The measurement result is transmitted to the processing device **102** by the control unit **111**.

A specimen preparing unit **113** is a mechanism for preparing the specimen for measurement from the sample to be analyzed. The specimen preparing unit **113** mixes the reagent in a reagent container set in the reagent rack **114** to the sample (blood plasma) to obtain a measurement specimen.

The barcode reading unit **115** reads a barcode given to the reagent container, and the like set in the reagent rack **114**. The barcode of the reagent container includes information for specifying the detailed information (information such as reagent name, type of reagent container, lot number, expiration date of reagent, etc.) of the reagent contained in the reagent container.

The detailed information of the reagent is transmitted to the processing device **102** by the control unit **111**, and managed in the processing device **102**.

As shown in FIG. **3**, the processing device **102** is a computer mainly configured from a display **102***a*, a main body **102***b*, and an input device **102***c*.

The main body **102***b* is mainly configured by a CPU (processing unit) **120**, a ROM **121**, a RAM **122**, a hard disk **123**, an input/output interface **124**, a readout device **125**, a communication interface **126**, and an image output interface **127**. The CPU **120**, the ROM **121**, the RAM **122**, the hard disk **123**, the input/output interface **124**, the readout device **125**, the communication interface (transmission unit) **126**, and the image output interface **127** are data communicably connected by a bus **128**.

The CPU (processing unit) **120** can execute a computer program stored in the ROM **121** as well as a computer program loaded in the RAM **122**. When the CPU **120** executes the application program, the function of the processing device **102** is realized and the computer functions as the processing device **102**.

The ROM **121** is configured by a mask ROM, a PROM, an EPROM, an EEPROM, and the like, and is recorded with the computer program to be executed by the CPU **120** and the data used for the same.

The RAM **122** is configured by a SRAM, a DRAM, and the like. The RAM **122** is used to read out the computer programs recorded in the ROM **121** and the hard disk **123**. The RAM **122** is used as a work region of the CPU **120** when executing the computer programs.

The hard disk **123** is installed with various computer programs (management program **123***b*) to be executed by the CPU **120** such as the operating system, the application program, and the like, and the data used for the execution of the relevant computer program.

The readout device **125** is configured by a flexible disk drive, a CD-ROM drive, a DVD-ROM drive, and the like, and can read out the computer program or the data recorded in a portable recording medium **130**.

The hard disk **123** includes a measurement parameter storage section **123***a* which is a region that stores a measurement parameter for describing a measurement protocol, the measurement parameter being used for the analysis of the sample, and a region that stores the application program (management program) **123***b*.

The management program **123***b* is a program for executing a measurement parameter registration process, a transmission management process, and other necessary processes, to be described later.

In the present embodiment, the measurement parameter storage section **123***a* is arranged in the processing device **102** of the analysis device **100**. However, the measurement parameter storage section **123***a* may be arranged in the management server **201**. In such a case, when registering the measurement protocol, the user first inputs a password, or the like and accesses the management server to perform the registration of the measurement protocol.

The input/output interface **124** is, for example, configured by a serial interface such as an USB, an IEEE 1394, a RS-232C, and the like; a parallel interface such as an SCSI, an IDE, an IEEE 1284, and the like; and an analog interface including a D/A converter, an A/D converter, and the like. An

input device **102***c* including a keyboard and a mouse is connected to the input/output interface **124**. The operator can input data to the main body **102***b* by using the input device **102***c*.

The communication interface **126** is, for example, the Ethernet (registered trademark) interface. The processing device **102** can transmit and receive data with the device main body **101** using a predetermined communication protocol by the communication interface **126**.

The communication interface **126** includes a wired communication section (wired transmission section) **126***a* and a wireless communication section (wireless transmission section) **126***b*. The communication interface **126** can carry out the connection to the network **300** through wired connection, or can carry out the connection through wireless connection. The wireless communication section **126***b* is configured as a wireless communication section for wireless LAN or a wireless communication section for mobile communication such as a cellular phone. The wireless communication section **126***b* can carry out the wireless communication with an access point (AP) **300***a* for wireless access, and can carry out communication with the management server **201** via the Internet **300**. The access point **300***a* may be an access point for the wireless LAN, or may be a base station for the cellular phone.

The image output interface **127** is connected to the display **102***a* configured by an LCD, a CRT, or the like. The CPU **120** outputs a video signal corresponding to the image data to the display **102***a* via the image output interface **127**. The display **102***a* displays an image (screen) according to the input video signal.

FIG. **4** shows a block diagram of the management server **201**. The management server **201** is a computer mainly configured by a main body **200***a*, a display **200***b*, and an input device **200***c*.

The main body **200***a* is mainly configured by a CPU **220**, a ROM **221**, a RAM **222**, a hard disk **223**, an input/output interface **224**, a readout device **225**, a communication interface **226**, and an image output interface **227**. The CPU **220**, the ROM **221**, the RAM **222**, the hard disk **223**, the input/output interface **224**, the readout device **225**, the communication interface **226**, and the image output interface **227** are data communicably connected by a bus **228**.

The CPU **220** can execute a computer program stored in the ROM **221** as well as a computer program loaded in the RAM **222**. When the CPU **220** executes the application program, the function of the management server **201** is realized and the computer functions as the management server **201**.

The ROM **221** is configured by a mask ROM, a PROM, an EPROM, an EEPROM, and the like, and is recorded with the computer program to be executed by the CPU **220** and the data used for the same.

The RAM **222** is configured by a SRAM, a DRAM, and the like. The RAM **222** is used to read out the computer programs recorded in the ROM **221** and the hard disk **223**. The RAM **222** is used as a work region of the CPU **220** when the computer programs are executed. The hard disk **223** is installed with various computer programs (management program **223***e*) to be executed by the CPU **220** such as the operating system, the application program, and the like, and the data used for the execution of the relevant computer program.

The readout device **225** is configured by a flexible disk drive, a CD-ROM drive, a DVD-ROM drive, and the like, and can read out the computer program or the data **230***a* recorded in a portable recording medium **230**.

The application program is not only provided by the portable recording medium **230**, and may be provided from an external device communicably connected to a computer by an electrical communication line (may be wired or wireless) through the electrical communication line. For example, if the application program is stored in a hard disk of a server computer on the Internet, the management device **200** may access the server computer, download the computer program, and install the computer program in the hard disk **223**.

The hard disk **223** is installed with an operating system that provides a graphical user interface environment of Windows (registered trademark) manufactured and sold by US Microsoft Co., for example. In the following description, the application program according to the present embodiment is assumed to operate on the relevant operating system.

Furthermore, the hard disk **223** includes a transmission information storage section **223***a* which is a region that stores transmission information transmitted from the analysis device, a region that stores a reference value database **223***b*, a region that stores a reagent database **223***c*, a region that stores a user database **223***d*, and a region that stores the application program (management program) **223***e*.

The reference value database **223***b* is a database showing a range (reference value) permitted on the management server **201** side as a set value of the measurement parameter. The reference value is a value recommended as the measurement parameter when a reagent manufacturer of the reagent used in the analysis device **100** uses the reagent manufactured by such reagent manufacturer in the analysis device **100**. The reagent manufacturer guarantees that appropriate measurement data can be obtained if the measurement parameter is set at such recommended value.

The reagent database **223***c* is a database in which the reagent having the possibility of being used in the analysis device **100** is registered. The reagent that is not registered in the reagent database **223***c* is sometimes used in the analysis device **100**.

The database **223***d* is stored with information associated with a user (inspection facility), the information being contact information (telephone number, e-mail address, address of inspection facility, name of contact personnel), and the like, in association with a device ID of the analysis device **100**.

The management program **223***e* is provided to execute the processes necessary to function as the management server such as the server process, and the like, to be described later.

The input/output interface **224** is, for example, configured by a serial interface such as an USB, an IEEE 1394, a RS-232C, and the like; a parallel interface such as an SCSI, an IDE, an IEEE 1284, and the like; and an analog interface including a D/A converter, an A/D converter, and the like. An input device **200***c* including a keyboard and a mouse is connected to the input/output interface **224**. The operator can input data to the main body **200***a* by using the input device **200***c*.

The communication interface **226** is, for example, the Ethernet (registered trademark) interface. The management device **201** can transmit and receive data with the analysis device **100** and the terminal device **202** of the support center D connected via the network **300** using a predetermined protocol by the communication interface **226**.

The image output interface **227** is connected to the display **200***b* configured by an LCD, a CRT, or the like. The CPU **220** outputs a video signal corresponding to the image data to the display **200***b* via the image output interface **227**. The display **200***b* displays an image (screen) according to the input video signal.

[2. Registration Process of Measurement Parameter]

The measurement parameter is stored in the measurement parameter storage section **123***a* of the processing device **102** as a measurement condition at a time when the measurement of the sample is performed using the reagent such as the dispensing amount, the reaction time, and the like of the reagent. The device main body **101** of the analysis device **100** analyzes (includes measurement) the sample in accordance with the measurement parameter stored in the measurement parameter storage section **123***a*.

The measurement parameter storage section **123***a* can store a plurality of measurement parameters corresponding to a plurality of reagents.

FIG. **5** and FIG. **6** show screens **400**, **500** for the registration (update, add, delete) process of the measurement parameter.

The registered content of the measurement parameter set for every reagent can be changed in accordance with various situations.

For example, even if the reagent is used for the same measurement item, the properties of the reagent differ if the actual producer (manufacturer of the reagent) of the reagent is different. Therefore, when changing the reagent to a reagent of a different manufacturer, a new measurement parameter for the relevant reagent needs to be additionally set.

Furthermore, even if the same reagent is continuously used, the measurement condition may be changed as necessary. In this case, the already set measurement parameter needs to be updated.

Furthermore, the measurement parameter for the reagent, which use is stopped, does not need to be remained set, and may be deleted.

According to the situation described above, the processing device **102** (processing unit **120**) of the analysis device **100** can display a reagent master setting screen for changing the measurement parameter shown in FIG. **5** on the display **102***a*.

The reagent master setting screen includes a reagent list display section **401**, a reagent information display section **402**, and an operation display section **403**.

The reagent list display section **401** displays a list showing a list of reagents registered in the processing device **102**. The reagent list display section **401** has fields such as a "reagent ID" **401***a*, a "reagent name" **401***b*, a "producer" **401***c*, and the like.

The "reagent ID" **401***a* is a field in which the ID for identifying the reagent is displayed, the "reagent name" **401***b* is a field in which the name of the reagent is displayed, and the "producer" **401***c* is a field in which the producer of the reagent is displayed.

The reagent information display section **402** displays information of the reagent (reagent name: ccc in FIG. **5**) selected in the reagent list display section **401**. The selection of the reagent in the reagent list display section **401** is carried out by the operation of the user for specifying the reagent desired to select in the list. The selected reagent is highlight (emphasize) displayed in the reagent list display section **401**.

The reagent information display section **402** also displays more detailed information associated with the selected reagent in addition to the information **402***a*, **402***b*, **402***c* corresponding to the information **401***a*, **401***b*, **401***c* displayed in the reagent list display section **401**.

In the present embodiment, the detailed information of the reagent obtained by reading the barcode of the reagent container with the barcode reading unit **115** is automatically reflected on the information of the reagent displayed in the reagent list display section **401** and the reagent information display section **402**, as well as, a measurement parameter setting screen **500**, to be described later, but may be manually input by the user.

The operation display section **403** includes a "delete" button **403***a*, a "register button" **403***b*, and a "close" button **403***c*.

The "delete" button **403***a* is provided to delete the reagent selected in the reagent list display section **401**.

The "register" button **403***b* is provided to register (save) the reagent information (includes measurement parameter) in the current setting content.

The "close" button **403***c* is provided to close the reagent master setting screen **400**.

The reagent information display section **402** includes a "set measurement parameter" button **402***d* for setting the measurement parameter to be set in association with the relevant reagent.

When the "set measurement parameter" button **402***d* is selected, the measurement parameter setting screen **500** shown in FIG. **6** is displayed.

In the measurement parameter setting screen **500**, a reagent ID **501** and a reagent name **502** of the reagent to which the measurement parameter is applied is displayed, and also a measurement item **503** in which the relevant reagent is used is displayed.

The measurement parameter setting screen **500** includes input boxes **504***a* to **504***h* for inputting set values of the plurality of measurement parameters. The values of the dispensing amount, the reaction time, and the like of the reagent are input to the input boxes **504***a* to **504***h* as set values of the measurement parameter. For example, when the measurement item is P-FDP (Fibrin/Fibrinogen Degradation Products), set values of sample aspiration amount, diluted solution amount, first reagent amount, warming time, second reagent amount, absorbance changing amount calculation start time, absorbance changing amount calculation end time, wavelength, and the like are input to the input boxes.

The processing for accepting the registration of the measurement parameter is carried out in the set parameter setting screen **500** as described above. The set value of the changed measurement parameter is registered in the measurement parameter storage section **123***a*.

The measurement parameter registration process by the processing device **102** (management program **123***b*) will now be described based on FIG. **7**.

As shown in FIG. **7**, when registering the measurement parameter in the analysis device **100**, the processing for accepting the input operation for the selection (includes new registration) of the reagent to be registered is first carried out (step S**1**). The selection of the reagent is carried out by selecting the displayed reagent in the reagent master setting screen **400** shown in FIG. **5** (step S**1**).

Next, the set measurement parameter button **402** of the reagent master setting screen **400** is selected, whereby the measurement parameter setting screen **500** of FIG. **6** is displayed. In such parameter setting screen **500**, the update/new registration (addition) of various types of set values to become the measurement parameter are carried out (step S**2**).

The registration type is "update" if the set value is changed to a new set value with the set value of the measurement parameter already set, and the registration types is "add" if the set value is newly set with the set value of the measurement parameter in the non-set state.

After the input of the set value in the measurement parameter setting screen **500** shown in FIG. **6** is terminated and the "register" button **403***b* of FIG. **5** is selected, the measurement parameter after the change (update/add) is registered in the measurement parameter storage section **123***a*.

When deleting the set measurement parameter, the "delete" button **403***a* is to be selected with the reagent to be desired to delete being selected in the reagent master setting screen **400** of FIG. **5**. Thus, the measurement parameter corresponding to the reagent is deleted with the reagent information. When the measurement parameter is deleted, the registration type is "delete".

When the registration of the measurement parameter has been carried out in the screens **400**, **500** of FIG. **5** and FIG. **6** (step S**3**), determination of the registration type is made (steps S**4**, S**6**, S**8**). When the registration type of the measurement parameter is "update" (step S**4**), the processing for transmitting to the management server **201** the transmission information including the updated measurement parameter from the wired communication section **126***a* or the wireless communication section **126***b* of the communication interface **126** is executed (step S**5**).

When the registration type of the measurement parameter is "add" (step S**6**), the processing for transmitting to the management server **201** the transmission information including the added measurement parameter from the wired communication section **126***a* or the wireless communication section **126***b* of the communication interface **126** is executed (step S**7**).

When the registration type of the measurement parameter is "delete" (step S**8**), the processing for transmitting to the management server **201** the transmission information including the deleted measurement parameter from the wired communication section **126***a* or the wireless communication section **126***b* of the communication interface **126** is executed (step S**9**).

The transmission information transmitted to the management server **201** has a data structure as shown in FIG. **8**. That is, the transmission information includes a device ID **601**, a registration type **602**, reagent information **603**, a transmission type **604**, and the like.

The device ID **601** is the identification information indicating the analysis device **100** that has transmitted the transmission information.

The registration type **602** is the information (information indicating a transmission cause) indicating the registration type of the measurement parameter, and indicates one of update, add, and delete. The registration type **602** is also the information indicating that the measurement parameter has been changed.

The reagent information **603** includes a reagent name **603***a*, a measurement item name **603***b*, and a plurality of set values **603***c*, **603***d*, **603***e*. The reagent name **603***a* indicates the name of the reagent corresponding to the registered measurement parameter. The measurement item name **603***b* indicates the measurement item name measured by the reagent corresponding to the registered measurement parameter. The set values **603***c*, **603***d*, **603***e* indicate each set value of the registered measurement parameters.

The transmission type **604** is the information indicating whether the transmission of the transmission information from the analysis device **100** is carried out by the wired communication or is carried out by the wireless communication. If the transmission information is transmitted using the wired communication section (wired transmission section) **126***a* of the communication interface (transmission unit) **126** in the processing device **102** of the analysis device **100**, the information indicating "wired" is stored in the transmission type **604**. If the transmission information is transmitted using the wireless communication section (wireless transmission section) **126***b*, the information indicating "wireless" is stored in the transmission type **604**.

The transmission information is also transmitted at a predetermined timing other than being transmitted with the registration of the measurement parameter as a trigger as in the previously described steps S**5**, S**7**, S**9**.

As shown in FIG. **9**, the processing device **102** (management program **123***b*) constantly monitors whether or not a transmission schedule set in advance is reached (step S**11**), and transmits the transmission information (step S**12**) when the predetermined transmission schedule (timing) set in advance is reached.

The predetermined transmission schedule is set as a timing at which a lot of the reagent used in the analysis device **100** is switched, for example. The switching of the lot of the reagent can be detected by reading the barcode of the reagent container with the barcode reading unit **115** when the reagent of a new lot number is set in the reagent rack **114** with the replacement of the reagent.

When the lot of the reagent is switched, the transmission information including the reagent information (measurement parameter) on such reagent is generated, and transmitted from the processing device **102** to the management server **201**. In such a case, the information indicating schedule transmission is set in the registration type **602** (information indicating transmission cause) of the transmission information rather than any one of update, add, or delete.

Since the transmission information is transmitted other than when the measurement parameter has been registered, the transmission frequency of the transmission information is increased and a great amount of information for management in the management server **201** is obtained.

The information (transmission information) associated with the reagent currently used in the analysis device **100** is transmitted other than when the measurement parameter has been registered such as at the time of switching of the lot of the reagent, and the like, so that the management server **201** can accurately grasp which reagent is currently being used.

The predetermined transmission schedule (timing) to transmit the transmission information may be the timing at which the reagent expired, and furthermore, may be an arbitrary date and time.

The management server **201** (management program **223***e*) for receiving the transmission information carries out the server process shown in FIG. **10**.

When receiving the transmission information from the analysis device **100** (receiving process; step S**21**), the management server **201** saves the transmission information in the transmission information storage section **223***a*. The measurement parameter included in the received transmission information is compared with the measurement parameter (transmission information) for the same reagent (measurement time) transmitted the previous time from the same analysis device **100**, and whether or not the measurement parameter is changed is determined (step S**22**). The determination of step S**22** may be made based on the registration type (information indicating the transmission cause) included in the received transmission information. That is, determination is made that there is change compared to the previous time if the registration type (information indicating the transmission cause) is update, add, or delete, and that there is no change in the measurement parameter if the registration type is the information indicating schedule transmission.

If there is change in the measurement parameter, the management server **201** assumes the received transmission information as the target of display. If there is no particular change, the management server **201** terminates the process without change. That is, if there is no change in the measurement parameter (such as in the case of schedule transmission, etc.),

the information is not the target of display at the management server **201** or the terminal **202**.

If there is change in the measurement parameter, the management server **201** determines whether the set value of the measurement parameter included in the received transmission information is within a range of the reference value registered in the reference value database **223***b*, or is beyond the range of the reference value (step S**23**).

After the determination of step S**23** or in accordance with the operation by the personnel in the support center D, a measurement parameter registration check screen **700** shown in FIG. **11** is displayed on the display of the management server **201** or the terminal **202**. In the measurement parameter registration check screen **700**, the display information associated with the reagent such as a reagent ID **701**, a reagent name **702**, a measurement item **703**, and the like is displayed based on the received transmission information, and in addition, set values **704***a* to **704***h* of the measurement parameter related to the registration are displayed (output process by the screen display; steps S**24**, S**25**). For example, when the measurement item is P-FDP, the set values of sample aspiration amount, diluted solution amount, first reagent amount, warming time, second reagent amount, absorbance changing amount calculation start time, absorbance changing amount calculation end time, wavelength, and the like are displayed.

The registration type (update, add, delete) of the measurement parameter may be displayed based on the received transmission information in the measurement parameter registration check screen **700**.

The personnel of the support center D can grasp that the measurement parameter has been registered in the analysis device **100** by viewing the screen **700**. As a result, if inappropriate measurement data is obtained using the analysis device **100**, whether or not the registration of the measurement protocol by the user is performed is also grasped, and hence whether or not the cause of inappropriateness is the registration of the measurement protocol can be verified. Accordingly, the measurement data of the analysis device **100** can be more accurately managed.

After the determination of step S**23** or in accordance with the operation by the personnel in the support center D, the measurement parameter registration check screen **700** shown in FIG. **11** is displayed on the display of the management sever **201** or the terminal **202**, but the present invention is not limited thereto. After the determination of step S**23**, the management sever **201** may transmit to the portable telephone of the personnel who performs the maintenance, and the like of the analysis device, the measurement protocol of which device in which facility has been registered by e-mail. The management server **201** may include a speaker, so that after the determination of step S**23**, the management server **201** may report to the personnel the measurement protocol of which device in which facility has been registered by audio from the speaker in the support center D. Thus, the registration of the measurement protocol is automatically output rather than according to the operation by the personnel in the support center D, so that the registration of the measurement protocol can be reported to the personnel of the support center D in a more timely and reliable manner.

The display information associated with the reagent such as the reagent ID **701**, and the like is generated by referencing the reagent database **233***c* based on the reagent name **603***a* included in the transmission information. The processing for referencing the reagent database **233***c* also serves as a processing for determining whether or not the reagent indicated by the reagent name **603***a* included in the transmission information is a predetermined reagent set in the management server **201** (management device **200**).

If the reagent indicated by the reagent name **603***a* included in the transmission information is the reagent (unknown reagent) that is not registered in the reagent database **233***c*, the information indicating that the measurement parameter has been set (registered) for the unknown reagent is displayed in the screen **700** in place of the display information associated with the reagent.

Thus, the personnel of the support center D can recognize the start of usage of the unknown reagent. In the case of the unknown reagent, the reference (reference value) for determining whether or not the registration of the measurement parameter is appropriate is poor, and hence attention is particularly needed for the appropriateness in the registration of the measurement parameter.

Furthermore, in the measurement parameter registration check screen **700**, the reference value **705** corresponding to a plurality of set values **704***a*, **704***b*, and **704***c* is displayed based on the reference value database **223***b*. The reference value **705** may not be displayed for the measurement parameter in which the reference value is not set in the reference value database **232***b*.

As shown in FIG. **11**, in the measurement parameter registration check screen **700**, the set values of the changed measurement parameter ("sample aspiration amount" **704***a*, "diluted solution amount" **704***b*, "first reagent amount" **704***c* of FIG. **11**) are emphasis displayed, and the set values of the measurement parameter ("sample aspiration amount" **704***a*, "first reagent amount" **704***c* of FIG. **11**) in which the set values of the measurement parameter included in the received transmission information are beyond the range of the reference value are emphasis displayed (step S**24**). The set value ("diluted solution amount" **704***b* of FIG. **11**) that simply has change and the set value ("sample aspiration amount" **704***a*, "first reagent amount" **704***c* of FIG. **11**) beyond the range of the reference value are emphasis displayed in a distinguishable manner (e.g., with different colors).

If all the set values of the changed measurement parameter are within the reference value, the emphasis display is made on the changed set values (step S**25**).

Thus, the personnel on the support center D side can easily determine if the registration of the measurement parameter is important or minor by determining whether or not the measurement parameter after the change exceeds the reference value in relation to the change in the measurement parameter, and then displaying the measurement parameter that exceeds the reference value and the measurement parameter that does not exceed the reference in a distinguished manner.

The registration of the measurement parameter in the range not exceeding the reference value may be assumed as a registration without any problem, and notification of registration may not be displayed even if the transmission information is received.

The determination on whether or not the registered measurement parameter exceeds the reference value is carried out on the analysis device **100** side, and the transmission information may be transmitted only for the registration of the measurement parameter exceeding the reference value. When making the determination based on the reference value on the analysis device **100** side, the reference value may be input/set on the analysis device **100** side or may be acquired by the analysis device **100** from the reference value database **223***b* of the management server **201**.

FIG. **12** shows a measurement parameter reference value setting screen **800** for setting the reference value of the measurement parameter at the management server **201** or the

terminal **202**. The reference value of the measurement parameter can be set for every reagent (measurement item).

Other than being input with a reagent ID **801**, a reagent name **802**, and a measurement item **803** of a reagent to become a target for setting the reference value of the measurement parameter, the measurement parameter reference value setting screen **800** can be input with a range (upper limit and lower limit) of the reference value for a plurality of set values **804***a* to **804** configuring the measurement parameter. For example, when the measurement item is P-FDP, the range (upper limit and lower limit) of the reference value for the set values of sample aspiration amount, diluted solution amount, first reagent amount, warming time, second reagent amount, absorbance changing amount calculation start time, absorbance changing amount calculation end time, wavelength, and the like can be input. The reference value set in the measurement parameter reference value setting screen **800** is registered in the reference value database **232***b*.

In the present embodiment, the configuration in which the reference value has a range (upper limit and lower limit) for the plurality of reference values **804***a* to **804***h* corresponding to the measurement parameter in the measurement parameter reference value setting screen **800** for setting the reference value of the measurement parameter has been described, but the present invention is not limited thereto. The present invention may be such that the reference value does not have a range and the reference value may be one reference value set in advance, for example.

In step S**24** or in both step S**24** and step S**25**, the contact information (e.g., telephone number or e-mail address) of the inspection facility, in which the analysis device **100** registered with the measurement parameter is set, is displayed on the display of the management server **201** or the terminal **202** of the support center D. The contact information is displayed based on the user database **223***d*.

Thus, for example, when the measurement parameter of the analysis device **100***c* of the inspection facility C is registered (and when the measurement parameter exceeds the reference value), the personnel of the support center D may make a call to the inspection facility C, send an e-mail, or visit the inspection facility C to call the attention of the inspection facility C on the appropriateness of the registration of the measurement parameter.

The management server **201** determines whether or not the analysis device **100** that is a source of the transmission transmits with the wireless communication section (wireless transmission section) **126***b* based on the transmission type **604** of the received transmission information. That is, if the transmission type **604** of the received transmission information indicates "wireless", it is apparent that the analysis device **100** that is a source of the transmission transmits the transmission information with the wireless communication section **126**.

If the transmission type **604** of the received transmission information indicates "wireless", the management server **201** performs a feedback output of reporting that the measurement parameter has been registered with respect to the analysis device **100** (step S**26**).

In the case of the analysis device that carries out communication with the management server **201** through the wireless communication as in the analysis device **100***a* of the facility A shown in FIG. **1**, there is a possibility that the analysis device **100***a* will be moved to various places in the inspection facility or outside the inspection facility. Thus, even if the support center D attempts to contact the contact information grasped based on the user database **223***d* to call the attention involved in the registration of the measurement parameter, there is a possibility that the contact cannot be made.

Thus, with respect to the analysis device **100***a* that carries out the communication with the management server **201** through the wireless communication, the feedback output is carried out with respect to the analysis device **100***a* to directly call the attention to the user of the analysis device **100***a*. The content displayed on the processing device **102** of the analysis device **100***a* with the feedback output may be similar to or simpler than the screen **700** of FIG. **11**.

The feedback output is preferably carried out only when the measurement parameter exceeds the reference value, but may be reported even when the reference value is not exceeded.

Furthermore, the feedback output may be carried out regardless of the transmission method (wireless/wired) of the analysis device **100**.

The present invention is not limited to the embodiment described above, and various modifications may be made.

What is claimed is:

1. An analysis system comprising:

an analysis device that analyzes a sample using a reagent and that performs the analysis of the sample in accordance with a measurement parameter measured in relation to a reagent to be used; and

a management device communicably connected to the analysis device via a network; wherein the analysis device includes a first control unit that enables execution of processing for accepting a registration of the measurement parameter, and when the measurement parameter is registered, executes processing for transmitting to the management device transmission information including information indicating that the measurement parameter is registered;

the management device includes a display unit and a second control unit that executes a receiving process of receiving the transmission information transmitted from the analysis device and an output process of outputting information indicating that the measurement parameter is registered in the analysis device based on the received transmission information, wherein:

the second control unit enables execution of processing which determines whether or not the registered measurement parameter exceeds a range of a predetermined reference value and for controlling the display unit to display the registered measurement parameter that exceeds the reference value and the registered measurement parameter that does not exceed the reference in a distinguished manner.

2. The analysis system according to claim **1**, wherein the transmission information includes information indicating a set value of a measurement parameter to be registered.

3. The analysis system according to claim **1**, wherein the transmission information includes information indicating a registration type of the measurement parameter.

4. The analysis system according to claim **1**, wherein the first control unit executes the processing for transmitting the set measurement parameter to the management device at a predetermined timing.

5. The analysis system according to claim **4**, wherein the predetermined timing is a timing at which a lot of a reagent is switched.

6. The analysis system according to claim **1**, wherein the transmission information includes identification information of the analysis device.

7. The analysis system according to claim 1, wherein the output process includes a process for feedback output of transmitting to the analysis device information for causing the analysis device to output the information indicating that the measurement parameter is registered in the analysis device with respect.

8. The analysis system according to claim 7, wherein

the analysis device includes a wireless transmission section that wirelessly transmits the transmission information;

the second control unit enables execution of processing for determining whether or not the transmission information is transmitted from the wireless transmission section; and

the feedback output is carried out when determined that the transmission information is transmitted from the wireless transmission section.

9. The analysis system according to claim 1, wherein the second control unit enables execution of processing for determining whether or not the set value of the registered measurement parameter is within a range of a predetermined reference value.

10. The analysis system according to claim 1, wherein the transmission information includes reagent information indicating a reagent corresponding to the measurement parameter; and

the second control unit enables execution of processing for determining whether or not a reagent indicated by the reagent information is a predetermined reagent set in the management device.

11. The analysis system according to claim 1, wherein the analysis device includes a storage unit that stores the measurement parameter; and

the first control unit enables execution of processing for accepting the registration of the measurement parameter stored in the storage unit.

12. The analysis system according to claim 1, wherein

the output process includes a process of causing the display unit to display the information that the measurement parameter is registered.

13. An analysis device that analyses a sample using a reagent and that performs the analysis of the sample in accordance with measurement parameter set in relation to a reagent to be used, the analysis device being communicably connected to a management device via a network; the analysis device comprising:

a first control unit that enables execution of processing for accepting registration of the measurement parameter, and when the measurement parameter is registered, executes processing for transmitting to the management device transmission information including information indicating that the measurement parameter is registered, wherein the transmission information includes information indicating a set value of a measurement parameter to be registered and the registered measurement parameter that exceeds the reference value and the registered measurement parameter that does not exceed the reference are displayed in a remote management device display in a distinguished manner.

14. The analysis device according to claim 13, wherein the transmission information includes information indicating a registration type of the measurement parameter.

15. The analysis device according to claim 13, wherein the control unit executes the processing for transmitting the set measurement parameter to the management device at a predetermined timing.

16. The analysis device according to claim 15, wherein the predetermined timing is a timing at which a lot of a reagent is switched.

17. A management device communicably connected via a network to an analysis device that analyses a sample using a reagent and that performs the analysis of the sample in accordance with measurement parameter set in relation to a reagent to be used, the management device comprising:

a display unit; and

a control unit that executes a receiving process of receiving transmission information including information indicating that the measurement parameter is registered in the analysis device from the analysis device, and an output process of outputting the information indicating that the measurement parameter is registered in the analysis device based on the received transmission information, wherein

the control unit enables execution of processing which determines whether or not the registered measurement parameter exceeds a range of a predetermined reference value and for controlling the display unit to display the registered measurement parameter that exceeds the reference value and the registered measurement parameter that does not exceed the reference in a distinguished manner.

18. The management device according to claim 17, wherein the transmission information includes information indicating a set value of a measurement parameter to be registered.

19. The management device according to claim 18, wherein the transmission information includes information indicating a registration type of the measurement parameter.

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